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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,945	01/14/2002	Binie V. Lipps	FWLPAT015US	5192

7590 06/22/2004

John R. Casperson
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EXAMINER	
COUNTS, GARY W	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 06/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/047,945	LIPPS ET AL.	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01/14/02*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to discovery of the presence of endogenous proteins, classified in class 435, subclass 327.

II. Claim 2, 7, and 8 drawn to use of saliva as a non-invasive source for detection and assay of endogenously present proteins, classified in class 435, subclass 7.92.

III. Claim 3, drawn to discovery that people having high levels of IgE show higher levels in comparison to controls, classified in class 436, subclass 501.

IV. Claim 4, drawn to composition of synthetic LT-10 for treatment of IgE implicated disorders, classified in class 435, subclass 6.

V. Claim 5, drawn to composition of synthetic LT-10 as a treatment for having high level of IgE, classified in class 424, subclass 278.1.

VI. Claim 6, drawn to people having elevated level of IgE, classified in class 435, subclass 366.

VII. Claims 9-18 drawn to a method for reducing serum proteins, classified in class 424, subclass 1.65.

2. Inventions I and II are independent and distinct inventions. Invention I relates to the discovery of the presence of endogenous proteins whereas Invention II relates to

the introduction of use of saliva as a non-invasive source for detection and assay of endogenously present proteins. Inventions I and II have different functions and would have different method steps.

3. Inventions I and III are independent and distinct inventions. Inventions I and III are directed to different discoveries. Invention III requires people having high levels of IgE show higher levels in comparison to controls and invention I does not require these limitations.

4. I IV and V are independent and distinct inventions. Invention I relates to the discovery of the presence of endogenous proteins whereas inventions IV and V are compositions that are not disclosed as capable of use with invention I.

5. I and VI are independent and distinct inventions. Invention I is related to the discovery of the presence of endogenous proteins whereas Invention VI is directed toward people. Further, Invention VI involves elevated level of insulin, LT-10 treatment and elevated levels of IgE and Invention I does not require these limitations.

6. Inventions I and VII are independent and distinct inventions. Invention I relates to the discovery of the presence of endogenous proteins whereas Invention VII is a method for reducing serum proteins.

7. Inventions II and III are independent and distinct inventions. Invention II relates to the introduction of use of saliva as non-invasive source for detection and assay of endogenously present proteins whereas Invention III is the discovery that people having high levels of IgE show higher levels in comparison to controls.

8. Inventions II, IV and V are independent and distinct inventions. Invention II relates to the introduction of use of saliva as non-invasive source for detection and assay of endogenously present proteins whereas inventions IV and V are compositions that are not disclosed as capable of use with invention II.

9. Inventions II and VI are independent and distinct inventions. Invention II relates to the introduction of use of saliva as non-invasive source for detection and assay of endogenously present proteins whereas Invention VI is directed toward people. Further, Invention VI involves elevated level of insulin, LT-10 treatment and elevated levels of IgE and Invention II does not require these limitations.

10. Inventions II and VII are independent and distinct inventions. Invention II relates to the introduction of use of saliva as non-invasive source for detection and assay of endogenously present proteins whereas Invention VII is a method for reducing serum proteins. Inventions II and VII require different method steps.

11. Inventions III, IV and V are independent and distinct inventions. Invention III is the discovery that people having high levels of IgE show higher levels in comparison to controls whereas inventions IV and V are compositions that are not disclosed as capable of use with invention III.

12. Inventions III, VI and VII are independent and distinct inventions. Invention III is the discovery that people having high levels of IgE show higher levels in comparison to controls whereas Invention VI is directed toward people. Further, Invention VI involves elevated level of insulin, LT-10 treatment and elevated levels of IgE and Invention III

does not require these limitations. Further, Invention VII is a method for reducing serum proteins.

13. Inventions IV and V are independent and distinct inventions. Inventions IV and V are independent and distinct inventions. Invention IV requires that the synthetic LT-10 consist of ten amino acids and Invention V does not require this limitation.

14. Inventions IV and VI are independent and distinct inventions. Invention IV is a composition of synthetic LT-10 whereas Invention VI is people having elevated levels of IgE.

15. Inventions IV and VII are independent and distinct inventions. Invention IV is a composition of synthetic LT-10 whereas Invention VII is a method for reducing serum proteins. Further, Invention VII does not require the ten amino acids as recited in invention IV.

16. Inventions V and VI are independent and distinct inventions. Invention V is a composition of synthetic LT-10 whereas invention VI is people having elevated level of IgE.

17. Inventions V and VII are independent and distinct inventions. Invention V is a composition of synthetic LT-10 whereas Invention VII is a method for reducing serum proteins. Invention VII requires an effective amount of peptide containing at least the first four amino acids from the N-terminal of the sequence Leu Lys Ala Met Asp Pro Thr Pro Pro Leu Trp Ile Lys Thr Glu and Invention V does not require this limitation.

18. Inventions VI and VII are independent and distinct inventions. Invention VI is directed toward People having elevated levels of IgE whereas invention VII is a method

for reducing serum proteins. Invention VII requires an effective amount of peptide containing at least the first four amino acids from the N-terminal of the sequence Leu Lys Ala Met Asp Pro Thr Pro Pro Leu Trp Ile Lys Thr Glu and Invention VI does not require this limitation.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for one group is not required for other restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

19. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Counts
Examiner
Art Unit 1641
June 18, 2004

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
06/21/04